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DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 710, 745, and 774

[Docket No. 160302176-6176-01]

RIN 0694-AG88

Implementation of the February 2015 Australia Group (AG) Intersessional Decisions and the June 2015 AG Plenary Understandings

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: The Bureau of Industry and Security (BIS) publishes this final rule to amend the Export Administration Regulations (EAR) to implement the recommendations presented at the February 2015 Australia Group (AG) intersessional implementation meeting, and later adopted pursuant to the AG silent approval procedure, and the understandings reached at the June 2015

AG Plenary meeting. This rule amends three Commerce Control List (CCL) entries to reflect the February 2015 intersessional recommendations that were adopted by the AG. Specifically, this rule amends the CCL entry that controls chemical precursors by adding the chemical diethylamine (C.A.S. 109-89-7), which was not previously identified on the AG's "Chemical Weapons Precursors" common control list. This rule also amends the CCL entry that controls certain human and zoonotic pathogens and toxins by adding two viruses that were not previously identified on the AG "List of Human and Animal Pathogens and Toxins for Export Control" and by updating the nomenclature of certain viruses that were already identified on this AG common control list. In addition, this rule amends the CCL entry that controls equipment capable of handling biological materials to reflect the AG intersessional updates to the controls on biocontainment chambers, isolators, and biological safety cabinets and the controls on aerosol inhalation equipment described on the AG "Control List of Dual-Use Biological Equipment and Related Technology and Software." Consistent with the understandings adopted at the June 2015 AG Plenary meeting, this rule also amends the CCL entry that controls equipment capable of handling biological materials by updating the controls on freeze-drying (lyophilization) equipment.

Finally, this rule amends the EAR to reflect the addition of Angola and Burma as States Parties to the Chemical Weapons Convention (CWC) and also amends the Chemical Weapons Convention Regulations (CWCR) to reflect the addition of these two countries as States Parties.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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SUPPLEMENTARY INFORMATION:

The Bureau of Industry and Security (BIS) is amending the Export Administration Regulations (EAR) to implement the recommendations presented at the Australia Group (AG) Intersessional meeting held in The Hague, Netherlands, on February 4, 2015, and adopted pursuant to the AG silent approval procedure in April 2015, and the understandings reached at the AG Plenary meeting held in Perth, Australia, from June 1-5, 2015. The AG is a multilateral forum consisting of 41 participating countries that maintain export controls on a list of chemicals, biological agents, and related equipment and technology that could be used in a chemical or biological weapons program. The AG periodically reviews items on its control list to enhance the effectiveness of participating governments' national controls and to achieve greater harmonization among these controls.

Amendments to the CCL based on the February 2015 AG Intersessional Recommendations

This rule amends three Export Control Classification Numbers (ECCNs) on the Commerce Control List (CCL) (see Supplement No. 1 to part 774 of the EAR), as described below, to reflect the February 2015 intersessional recommendations that were adopted by the AG.

Amendments to ECCN 1C350 (precursor chemicals)

This final rule amends ECCN 1C350 on the CCL, to reflect the addition of the chemical diethylamine (C.A.S. 109-89-7) to the AG's "Chemical Weapons Precursors" common control list, by adding this chemical to 1C350.d, which controls precursor chemicals identified on the AG common control list that are not also "scheduled" chemicals (i.e., chemicals identified as Schedule 1, Schedule 2, or Schedule 3 chemicals) under the Chemical Weapons Convention (CWC).

Like the other precursor chemicals controlled under ECCN 1C350.d, diethylamine requires a license for chemical/biological (CB) reasons to destinations indicated under CB Column 2 on the Commerce Country Chart (see Supplement No. 1 to part 738 of the EAR) and for anti-terrorism (AT) reasons to destinations in Country Group E:1 (see Supplement No. 1 to part 742 of the EAR). Because none of the precursor chemicals controlled under ECCN 1C350.d (including diethylamine) are identified as "scheduled" chemicals under the CWC, these precursor chemicals do not require a license for chemical weapons (CW) reasons. (See part 742 of the EAR for additional information on the AT controls that apply to Iran, North Korea, Sudan, and Syria. See part 746 of the EAR for additional information on the sanctions that apply to Iran, North Korea, and Syria.)

Amendments to ECCN 1C351 (human and animal pathogens and “toxins”)

This final rule amends ECCN 1C351 on the CCL to reflect the addition of two viruses (severe acute respiratory syndrome-related coronavirus, a.k.a. SARS-related coronavirus, and reconstructed 1918 influenza virus) that were not previously identified on the AG “List of Human and Animal Pathogens and Toxins for Export Control” and to update the nomenclature for seventeen viruses that were already identified on this AG common control list and in ECCN 1C351.a (nineteen viruses were updated on the AG common control list, but only seventeen viruses in ECCN 1C351.a required updating). Prior to the publication of this final rule, the two viruses that are being added to ECCN 1C351.a were listed under ECCN 1C351.b, which controls viruses identified on the “select agents” lists maintained by the Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture, and the Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, but not identified on the AG “List of Human and Animal Pathogens and Toxins for Export Control.”

The license requirements applicable to the viruses affected by the amendments in this final rule (including the two viruses that are being moved from 1C351.b to 1C351.a) remain unchanged. Specifically, all of these viruses continue to require a license for CB reasons to destinations indicated under CB Column 1 on the Commerce Country Chart and for AT reasons to destinations indicated in AT Column 1 on the Commerce Country Chart.

This final rule also makes conforming changes to ECCN 1C351 by renumbering certain items in ECCN 1C351.a to reflect the addition of the two aforementioned viruses (i.e., the SARS-related coronavirus and the reconstructed 1918 influenza virus) and the updates to the nomenclature for seventeen other viruses listed in 1C351.a. The following table lists the viruses that are controlled under ECCN 1C351.a, as a result of the amendments made by this final rule, and indicates the previous and current names and CCL designations for each of these viruses. The names and CCL designations of thirteen viruses were not affected by this rule (these viruses continue to be designated as 1C351.a.1 through .a.8 and 1C351.a.42 through .a.46, as indicated in the following table). Twenty-six additional viruses in 1C351.a, whose names are not updated by this rule, have new CCL designations. All seventeen of the viruses in 1C351.a whose names are updated by this final rule also have new CCL designations, as do the two aforementioned viruses that are being moved from 1C351.b to 1C351.a (both of whose names are updated, as well).

Previous Names of AG-Controlled Viruses	Current Names of AG-Controlled Viruses	Previous CCL Designation	Current CCL Designation
African horse sickness virus	NO CHANGE	ECCN 1C351.a.1	NO CHANGE
African swine fever virus	NO CHANGE	ECCN 1C351.a.2	NO CHANGE
Andes virus	NO CHANGE	ECCN 1C351.a.3	NO CHANGE
Avian influenza virus	NO CHANGE	ECCN 1C351.a.4	NO CHANGE
Bluetongue virus	NO CHANGE	ECCN 1C351.a.5	NO CHANGE

Chapare virus	No CHANGE	ECCN 1C351.a.6	No CHANGE
Chikungunya virus	No CHANGE	ECCN 1C351.a.7	No CHANGE
Choclo virus	No CHANGE	ECCN 1C351.a.8	No CHANGE
Congo-Crimean haemorrhagic fever virus	Crimean-Congo hemorrhagic fever virus	ECCN 1C351.a.9	ECCN 1C351.a.10
Dengue fever virus	Dengue virus	ECCN 1C351.a.10	ECCN 1C351.a.11
Dobrava-Belgrade virus	No CHANGE	ECCN 1C351.a.11	ECCN 1C351.a.12
Eastern equine encephalitis virus	No CHANGE	ECCN 1C351.a.12	ECCN 1C351.a.13
Ebola virus	Ebolavirus (includes all members of the Ebolavirus genus)	ECCN 1C351.a.13	ECCN 1C351.a.14
Foot and mouth disease virus	Foot-and-mouth disease virus	ECCN 1C351.a.14	ECCN 1C351.a.15
Goat pox virus	Goatpox virus	ECCN 1C351.a.15	ECCN 1C351.a.16
Guanarito virus	No CHANGE	ECCN 1C351.a.16	ECCN 1C351.a.17
Hantaan virus	No CHANGE	ECCN 1C351.a.17	ECCN 1C351.a.18
Hendra virus (Equine	No CHANGE	ECCN 1C351.a.18	ECCN 1C351.a.19

morbillivirus)			
Herpes virus (Aujeszky's disease)	Suid herpesvirus 1 (Pseudorabies virus; Aujeszky's disease)	ECCN 1C351.a.19	ECCN 1C351.a.51
Hog cholera virus (syn.: swine fever virus)	Classical swine fever virus (Hog cholera virus)	ECCN 1C351.a.20	ECCN 1C351.a.9
Japanese encephalitis virus	NO CHANGE	ECCN 1C351.a.21	ECCN 1C351.a.20
Junin virus	NO CHANGE	ECCN 1C351.a.22	ECCN 1C351.a.21
Kyasanur Forest virus	Kyasanur Forest disease virus	ECCN 1C351.a.23	ECCN 1C351.a.22
Laguna Negra virus	NO CHANGE	ECCN 1C351.a.24	ECCN 1C351.a.23
Lassa fever virus	Lassa virus	ECCN 1C351.a.25	ECCN 1C351.a.24
Louping ill virus	NO CHANGE	ECCN 1C351.a.26	ECCN 1C351.a.25
Lujo virus	NO CHANGE	ECCN 1C351.a.27	ECCN 1C351.a.26
Lumpy skin disease virus	NO CHANGE	ECCN 1C352.a.28	ECCN 1C351.a.27
Lymphocytic	NO CHANGE	ECCN 1C351.a.29	ECCN 1C351.a.28

choriomeningitis virus			
Machupo virus	NO CHANGE	ECCN 1C351.a.30	ECCN 1C351.a.29
Marburg virus	Marburgvirus (includes all members of the Marburgvirus genus)	ECCN 1C351.a.31	ECCN 1C351.a.30
Monkey pox virus	Monkeypox virus	ECCN 1C351.a.32	ECCN 1C351.a.31
Murray Valley encephalitis virus	NO CHANGE	ECCN 1C351.a.33	ECCN 1C351.a.32
Newcastle disease virus	NO CHANGE	ECCN 1C351.a.34	ECCN 1C351.a.33
Nipah virus	NO CHANGE	ECCN 1C351.a.35	ECCN 1C351.a.34
Omsk haemorrhagic fever virus	Omsk hemorrhagic fever virus	ECCN 1C351.a.36	ECCN 1C351.a.35
Oropouche virus	NO CHANGE	ECCN 1C351.a.37	ECCN 1C351.a.36
Peste des petits ruminants virus	Peste-des-petits ruminants virus	ECCN 1C351.a.38	ECCN 1C351.a.37
Porcine enterovirus type 9 (syn.: swine vesicular disease virus)	Swine vesicular disease virus	ECCN 1C351.a.39	ECCN 1C351.a.52

Powassan virus	No CHANGE	ECCN 1C351.a.40	ECCN 1C351.a.39
Rabies virus and other members of the Lyssavirus genus	No CHANGE	ECCN 1C351.a.41	ECCN 1C351.a.40
Reconstructed replication competent forms of the 1918 pandemic influenza virus	Reconstructed 1918 influenza virus	ECCN 1C351.b.1	ECCN 1C351.a.41
Rift Valley fever virus	No CHANGE	ECCN 1C351.a.42	No CHANGE
Rinderpest virus	No CHANGE	ECCN 1C351.a.43	No CHANGE
Rocio virus	No CHANGE	ECCN 1C351.a.44	No CHANGE
Sabia virus	No CHANGE	ECCN 1C351.a.45	No CHANGE
SARS-associated coronavirus (SARS-CoV)	Severe acute respiratory syndrome-related coronavirus (SARS-related coronavirus)	ECCN 1C351.b.2	ECCN 1C351.a.47
Seoul virus	No CHANGE	ECCN 1C351.a.46	No CHANGE
Sheep pox virus	Sheeppox virus	ECCN 1C351.a.47	ECCN 1C351.a.48
Sin nombre virus	Sin Nombre virus	ECCN 1C351.a.48	ECCN 1C351.a.49

St. Louis encephalitis virus	NO CHANGE (correction needed on AG common control list, only)	ECCN 1C351.a.49	ECCN 1C351.a.50
Teschen disease virus	Porcine Teschovirus	ECCN 1C351.a.50	ECCN 1C351.a.38
Tick-borne encephalitis virus (Russian Spring-Summer encephalitis virus)	NO CHANGE (correction needed on AG common control list, only)	ECCN 1C351.a.51	ECCN 1C351.a.53
Variola virus	NO CHANGE	ECCN 1C351.a.52	ECCN 1C351.a.54
Venezuelan equine encephalitis virus	NO CHANGE	ECCN 1C351.a.53	ECCN 1C351.a.55
Vesicular stomatitis virus	NO CHANGE	ECCN 1C351.a.54	ECCN 1C351.a.56
Western equine encephalitis virus	NO CHANGE	ECCN 1C351.a.55	ECCN 1C351.a.57
Yellow fever virus	NO CHANGE	ECCN 1C351.a.56	ECCN 1C351.a.58

With the transfer of two viruses (i.e., severe acute respiratory syndrome-related coronavirus, a.k.a. SARS-related coronavirus, and reconstructed 1918 influenza virus) from ECCN 1C351.b to 1C351.a by this rule, only one virus continues to be controlled under 1C351.b: Tick-borne encephalitis virus (Siberian subtype, formerly West Siberian virus), which is listed in 1C351.b.3.

This rule makes a conforming change to ECCN 1C351.b.3 by updating the cross reference therein to tick-borne encephalitis virus (Far Eastern subtype, formerly known as Russian Spring-Summer encephalitis virus) to reflect the re-designation of that virus (now listed under ECCN 1C351.a.53) by the amendments to ECCN 1C351.a described above.

Amendments to ECCN 2B352 (equipment capable of use in handling biological materials)

This final rule amends ECCN 2B352 on the CCL to reflect changes to the AG “Control List of Dual-Use Biological Equipment and Related Technology and Software” based on the February 2015 intersessional recommendations that were adopted by the AG. Specifically, this rule amends the controls on biocontainment chambers, isolators, and biological safety cabinets described in 2B352.g.2 to more fully identify the characteristics that such equipment must possess in order to be controlled under ECCN 2B352. As amended by this rule, ECCN 2B352.g.2 controls biocontainment chambers, isolators, or biological safety cabinets having all of the following characteristics, for normal operation: (i) a fully enclosed workspace where the operator is separated from the work by a physical barrier; (ii) the ability to operate at negative pressure; (iii) the means to safely manipulate items in the workspace; and (iv) the supply and exhaust air to and from the workspace is high-efficiency particulate air (HEPA) filtered.

Consistent with the AG intersessional changes described above, this rule also adds two notes to ECCN 2B352 to further clarify the scope of the controls in 2B352.g.2. Note 1 to ECCN 2B352.g.2 indicates that the items subject to these controls include class III biosafety cabinets, as specified in the World Health Organization (WHO) Laboratory Biosafety Manual (3rd edition,

Geneva, 2004) or constructed in accordance with national standards, regulations or guidance. Note 2 to ECCN 2B352.g.2 indicates that these controls do not apply to isolators specially designed for barrier nursing or transportation of infected patients.

This rule also amends the controls on aerosol inhalation equipment described in ECCN 2B352.h to include nose-only exposure apparatus. As amended by this final rule, ECCN 2B352.h now controls the following aerosol inhalation equipment designed for aerosol challenge testing with microorganisms, viruses or toxins: (i) whole-body exposure chambers having a capacity of 1 cubic meter or greater; and (ii) nose-only exposure apparatus utilizing directed aerosol flow and having a capacity for the exposure of 12 or more rodents, or 2 or more animals other than rodents, and closed animal restraint tubes designed for use with such apparatus.

All items controlled under ECCN 2B352 require a license for CB reasons to destinations indicated under CB Column 2 on the Commerce Country Chart and for AT reasons to destinations indicated in AT Column 1 on the Commerce Country Chart.

Amendments to the CCL based on the June 2015 AG Plenary Understandings

Amendments to ECCN 2B352 (equipment capable of use in handling biological materials)

This final rule also amends ECCN 2B352 on the CCL to reflect changes to the AG “Control List of Dual-Use Biological Equipment and Related Technology and Software” based on the understandings reached at the June 2015 AG Plenary meeting. Specifically, this rule amends

2B352.e to control steam, gas or vapor sterilizable freeze-drying equipment with a condenser capacity of 10 kg of ice or greater in 24 hours (10 liters of water or greater in 24 hours) and less than 1000 kg of ice in 24 hours (less than 1,000 liters of water in 24 hours). This change is being made in recognition of the increasing viability of gas or vapor sterilizable freeze-drying equipment as an efficient and low-cost alternative to steam sterilization.

Conforming Change to ECCN 1C351 (human and animal pathogens and “toxins”)

In addition to the AG plenary and intersessional changes described above, this rule amends ECCN 1C351 by adding a fifth note to the License Requirement Notes in the License Requirements section of this ECCN. This new License Requirement Note is intended to provide guidance, consistent with the AG “List of Human and Animal Pathogens and Toxins for Export Control,” in determining whether a particular pathogen or “toxin” is controlled under ECCN 1C351. License Requirement Note 5 reads as follows:

Biological agents and pathogens are controlled under ECCN 1C351 when they are an isolated live culture of a pathogen agent, or a preparation of a toxin agent that has been isolated or extracted from any source or material, including living material that has been deliberately inoculated or contaminated with the agent. Isolated live cultures of a pathogen agent include live cultures in dormant form or in dried preparations, whether the agent is natural, enhanced or modified.

Addition of Angola and Burma as States Parties to the Chemical Weapons Convention

(CWC).

This rule also amends the EAR to reflect the addition of Angola and Burma as States Parties to the CWC on October 16, 2015, and August 7, 2015, respectively. Specifically, this rule amends Supplement No. 2 to part 745 of the EAR (States Parties to the CWC) to add Angola and Burma in alphabetical order. Because Angola and Burma are not AG participating countries, their addition to the list of CWC States Parties in Supplement No. 2 to part 745 does not affect the CB Column 1 and CB Column 2 license requirements for these countries that are indicated in Supplement No. 1 to part 738 of the EAR (Commerce Country Chart). The CB Column 3 license requirements indicated for Burma, in the Commerce Country Chart, also continue to apply. However, a license is no longer required for CB or CW reasons for exports to Angola or Burma of mixtures and test kits controlled under ECCN 1C395.a and .b, respectively, although a license would be required if any of the end-user or end-use requirements in part 744 of the EAR apply.

In order to maintain consistency between the EAR and the Chemical Weapons Convention Regulations (CWCR) (15 CFR parts 710-721), with respect to those countries that are identified as States Parties to the CWC, this rule also amends Supplement No. 1 to part 710 of the CWCR (States Parties to the CWC) to add Angola and Burma in alphabetical order.

Effect of this rule on the scope of the CB controls in the EAR

The changes made by this rule only marginally affect the scope of the EAR controls on precursor

chemicals, human and animal pathogens/toxins, and equipment capable of use in handling biological materials.

The amendments to ECCN 1C350, which add the chemical diethylamine (C.A.S. 109-89-7), are expected to have only a small impact on the scope of the CB controls in this ECCN. This chemical has corrosive properties that, in combination with its flammable characteristics, cause it to be categorized as a hazardous substance. As such, this chemical is regulated by the Occupational Safety and Health Administration (OSHA), the Drug Enforcement Administration (DEA), and the Environmental Protection Agency (EPA) and also is listed in the Department of Transportation's (DOT) Hazardous Materials Table (see 49 CFR 171.101). For these reasons, together with the limited number of commercial applications for this chemical, there is a relatively low volume of exports of this chemical from the United States. Therefore, the addition of this chemical to ECCN 1C350 is not expected to have a significant impact on the number of export license applications that must be submitted to BIS for items controlled under this ECCN.

The scope of the CCL-based CB controls on human and animal pathogens and toxins was not affected by the addition of two viruses (i.e., severe acute respiratory syndrome-related coronavirus, a.k.a. SARS-related coronavirus, and reconstructed 1918 influenza virus) to ECCN 1C351.a because these viruses were controlled under ECCN 1C351.b prior to the publication of this rule, and the license requirements that apply to items listed under 1C351.a are identical to those that apply to items listed under 1C351.b. Therefore, these changes are not expected to have a significant impact on the number of license applications that will have to be submitted for such items.

The addition of new License Requirement Note 5 to ECCN 1C351 is merely intended to provide guidance, consistent with the AG “List of Human and Animal Pathogens and Toxins for Export Control,” for determining whether a particular pathogen or “toxin” is controlled under this ECCN. It does not affect the scope of the controls of this ECCN and, therefore, is not expected to have any discernable effect on the number of license applications that will have to be submitted for items controlled under ECCN 1C351.

Although the updates in this rule to the controls on freeze-drying (lyophilization) equipment (see ECCN 2B352.e), biocontainment chambers, isolators, and biological safety cabinets (see ECCN 2B352.g.2) and aerosol inhalation equipment (see ECCN 2B352.h) represent an expansion in the number of items that require a license under ECCN 2B352, the expanded controls apply to only a relatively small percentage of these types of items that were not controlled under ECCN 2B352 prior to the publication of this rule. Consequently, any increase in the number of license applications resulting from this change is not expected to be significant, when considered as a percentage of these types of items.

Finally, the amendments adding Angola and Burma to Supplement No. 2 to part 745 of the EAR (States Parties to the CWC) and Supplement No. 1 to part 710 of the CWC are expected to have only a small impact on the scope of the controls applicable to exports to these countries of items on the CCL that are also identified on the AG common control lists. Because Angola and Burma are not AG participating countries, the CB Column 1 and CB Column 2 license requirements for these countries, as indicated in Supplement No. 1 to part 738 of the EAR

(Commerce Country Chart), continue to apply. In addition, the CB Column 3 license requirements indicated for Burma, in the Commerce Country Chart, continue to apply.

However, under ECCN 1C395, a license is no longer required for CB or CW reasons for exports to Angola or Burma of mixtures and test kits controlled by ECCN 1C395.a and .b, respectively. Therefore, collectively, these changes are expected to result in a small decrease in the number of license applications that will have to be submitted for these two countries.

Although the Export Administration Act expired on August 20, 2001, the President, through Executive Order 13222 of August 17, 2001, 3 CFR, 2001 Comp., p. 783 (2002), as amended by Executive Order 13637 of March 8, 2013, 78 FR 16129 (March 13, 2013), and as extended by the Notice of August 7, 2015 (80 Fed. Reg. 48233 (Aug. 11, 2015)), has continued the Export Administration Regulations in effect under the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*). BIS continues to carry out the provisions of the Export Administration Act, as appropriate and to the extent permitted by law, pursuant to Executive Order 13222 as amended by Executive Order 13637.

Rulemaking Requirements

1. Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and

of promoting flexibility. This rule has been designated a “significant regulatory action,” although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

2. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This rule contains a collection of information subject to the requirements of the PRA. This collection has been approved by OMB under Control Number 0694-0088 (Multi-Purpose Application), which carries a burden hour estimate of 58 minutes to prepare and submit form BIS-748. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to Jasmeet Seehra, Office of Management and Budget, by e-mail to Jasmeet_K._Seehra@omb.eop.gov or by fax to (202) 395-7285; and to the Regulatory Policy Division, Bureau of Industry and Security, Department of Commerce, 14th Street & Pennsylvania Avenue, N.W., Room 2705, Washington, DC 20230 or by e-mail to RPD2@bis.doc.gov.

3. This rule does not contain policies with Federalism implications as that term is defined in Executive Order 13132.

4. The provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring

notice of proposed rulemaking, the opportunity for public participation, and a delay in effective date, are inapplicable because this regulation involves a military and foreign affairs function of the United States (see 5 U.S.C. 553(a)(1)). Immediate implementation of these amendments is non-discretionary and fulfills the United States' international obligation to the Australia Group (AG). The AG contributes to international security and regional stability through the harmonization of export controls and seeks to ensure that exports do not contribute to the development of chemical and biological weapons. The AG consists of 41 member countries that act on a consensus basis and the amendments set forth in this rule implement changes made to the AG common control lists (as a result of the adoption of the recommendations made at the February 2015 AG intersessional meeting and the understandings reached at the June 2015 AG plenary meeting) and other changes that are necessary to ensure consistency with the controls maintained by the AG. Because the United States is a significant exporter of the items in this rule, immediate implementation of this provision is necessary for the AG to achieve its purpose. Any delay in implementation will create a disruption in the movement of affected items globally because of disharmony between export control measures implemented by AG members, resulting in tension between member countries. Export controls work best when all countries implement the same export controls in a timely manner.

Further, no other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this final rule. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule under the Administrative Procedure Act or by any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable. Therefore, this regulation is issued in

final form.

List of Subjects

15 CFR Part 710

Chemicals, Exports, Foreign Trade, Imports, Treaties.

15 CFR Part 745

Administrative practice and procedure, Chemicals, Exports, Foreign trade, Reporting and recordkeeping requirements.

15 CFR Part 774

Exports, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, part 710 of the Chemical Weapons Convention Regulations (15 CFR parts 710-721) and parts 745 and 774 of the Export Administration Regulations (15 CFR parts 730-774) are amended as follows:

PART 710 – [AMENDED]

1. The authority citation for Part 710 continues to read as follows:

Authority: 22 U.S.C. 6701 *et seq.*; E.O. 13128, 64 FR 36703, 3 CFR 1999 Comp., p. 199.

2. Supplement No. 1 to Part 710 is amended by revising the undesignated center heading “List of States Parties as of November 1, 2013” to read “List of States Parties as of June 1, 2016” and by adding, in alphabetical order, the countries “Angola” and “Burma”.

PART 745 – [AMENDED]

3. The authority citation for Part 745 continues to read as follows:

Authority: 50 U.S.C. 1701 *et seq.*; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; Notice of November 12, 2015, 80 FR 70667 (November 13, 2015).

4. Supplement No. 2 to Part 745 is amended by revising the undesignated center heading “List of States Parties as of November 1, 2013” to read “List of States Parties as of June 1, 2016” and by adding, in alphabetical order, the countries “Angola” and “Burma”.

PART 774 - [AMENDED]

5. The authority citation for Part 774 continues to read as follows:

Authority: 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; 10 U.S.C. 7420; 10 U.S.C. 7430(e); 22 U.S.C. 287c, 22 U.S.C. 3201 *et seq.*; 22 U.S.C. 6004; 30 U.S.C. 185(s), 185(u); 42 U.S.C. 2139a; 43 U.S.C. 1354; 15 U.S.C. 1824a; 50 U.S.C. 4305; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 7, 2015, 80 FR 48233 (August 11, 2015).

6. In Supplement No. 1 to Part 774, Category 1--Special Materials and Related Equipment, Chemicals, "Microorganisms" and "Toxins," ECCN 1C350 is amended by revising paragraph d.24 and adding a new paragraph d.25 in the "Items" paragraph, under the "List of Items Controlled" section, to read as follows:

Supplement No. 1 to Part 774 – The Commerce Control List

* * * * *

1C350 Chemicals that may be used as precursors for toxic chemical agents (see List of Items Controlled).

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List of Items Controlled

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Items:

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d. * * *

d.24. (C.A.S. #16893-85-9) Sodium hexafluorosilicate;

d.25. (C.A.S. #109-89-7) Diethylamine.

7. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 1--
Special Materials and Related Equipment, Chemicals, "Microorganisms" and "Toxins," ECCN
1C351 is amended by adding a Note 5 to the "License Requirement Notes," under the "License
Requirements" section, and by revising paragraphs a. and b. in the "Items" paragraph, under the
"List of Items Controlled" section, to read as follows:

1C351 Human and animal pathogens and "toxins", as follows (see List of Items Controlled).

License Requirements

* * * * *

License Requirement Notes: * * *

5. Biological agents and pathogens are controlled under this ECCN 1C351 when they are an isolated live culture of a pathogen agent, or a preparation of a toxin agent that has been isolated or extracted from any source or material, including living material that has been deliberately inoculated or contaminated with the agent. Isolated live cultures of a pathogen agent include live cultures in dormant form or in dried preparations, whether the agent is natural, enhanced or modified.

List of Items Controlled

* * * * *

Items:

a. Viruses identified on the Australia Group (AG) “List of Human and Animal Pathogens and Toxins for Export Control,” as follows:

a.1. African horse sickness virus;

a.2. African swine fever virus;

a.3. Andes virus;

a.4. Avian influenza (AI) viruses identified as having high pathogenicity (HP), as

follows:

a.4.a. AI viruses that have an intravenous pathogenicity index (IVPI) in 6-week-old chickens greater than 1.2; *or*

a.4.b. AI viruses that cause at least 75% mortality in 4- to 8-week-old chickens infected intravenously.

Note: *Avian influenza (AI) viruses of the H5 or H7 subtype that do not have either of the characteristics described in 1C352.a.4 (specifically, 1C352.a.4.a or a.4.b) should be sequenced to determine whether multiple basic amino acids are present at the cleavage site of the haemagglutinin molecule (HA0). If the amino acid motif is similar to that observed for other HPAI isolates, then the isolate being tested should be considered as HPAI and the virus is controlled under 1C352.a.4.*

- a.5. Bluetongue virus;
- a.6. Chapare virus;
- a.7. Chikungunya virus;
- a.8. Choclo virus;
- a.9. Classical swine fever virus (Hog cholera virus);
- a.10. Crimean-Congo hemorrhagic fever virus;
- a.11. Dengue virus;
- a.12. Dobrava-Belgrade virus;
- a.13. Eastern equine encephalitis virus;
- a.14. Ebolavirus (includes all members of the Ebolavirus genus);
- a.15. Foot-and-mouth disease virus;
- a.16. Goatpox virus;
- a.17. Guanarito virus;
- a.18. Hantaan virus;
- a.19. Hendra virus (Equine morbillivirus);
- a.20. Japanese encephalitis virus;

- a.21. Junin virus;
- a.22. Kyasanur Forest disease virus;
- a.23. Laguna Negra virus;
- a.24. Lassa virus;
- a.25. Louping ill virus;
- a.26. Lujo virus;
- a.27. Lumpy skin disease virus;
- a.28. Lymphocytic choriomeningitis virus;
- a.29. Machupo virus;
- a.30. Marburgvirus (includes all members of the Marburgvirus genus);
- a.31. Monkeypox virus;
- a.32. Murray Valley encephalitis virus;
- a.33. Newcastle disease virus;
- a.34. Nipah virus;
- a.35. Omsk hemorrhagic fever virus;
- a.36. Oropouche virus;
- a.37. Peste-des-petits ruminants virus;
- a.38. Porcine Teschovirus;
- a.39. Powassan virus;
- a.40. Rabies virus and all other members of the Lyssavirus genus;
- a.41. Reconstructed 1918 influenza virus;

Technical Note: 1C351.a.41 includes reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments.

- a.42. Rift Valley fever virus;
- a.43. Rinderpest virus;
- a.44. Rocio virus;
- a.45. Sabia virus;
- a.46. Seoul virus;
- a.47. Severe acute respiratory syndrome-related coronavirus (SARS-related coronavirus);
- a.48. Sheepox virus;
- a.49. Sin Nombre virus;
- a.50. St. Louis encephalitis virus;
- a.51. Suid herpesvirus 1 (Pseudorabies virus; Aujeszky's disease);
- a.52. Swine vesicular disease virus;
- a.53. Tick-borne encephalitis virus (Far Eastern subtype, formerly known as Russian Spring-Summer encephalitis virus—see 1C351.b.3 for Siberian subtype);
- a.54. Variola virus;
- a.55. Venezuelan equine encephalitis virus;
- a.56. Vesicular stomatitis virus;
- a.57. Western equine encephalitis virus; *or*
- a.58. Yellow fever virus.

b. Viruses identified on the APHIS/CDC “select agents” lists (see Related Controls paragraph #2 for this ECCN), but not identified on the Australia Group (AG) “List of Human and Animal Pathogens and Toxins for Export Control,” as follows:

b.1. [RESERVED];

b.2. [RESERVED]; *or*

b.3. Tick-borne encephalitis virus (Siberian subtype, formerly West Siberian virus—see 1C351.a.53 for Far Eastern subtype).

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8. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 2 -- Materials Processing, ECCN 2B352 is amended in the “Items” paragraph, under the List of Items Controlled section, by revising paragraph e., by revising paragraph g.2., by adding Notes 1 and 2 to paragraph g.2., and by revising paragraph h., to read as follows:

2B352 Equipment capable of use in handling biological materials, as follows (see List of Items Controlled).

* * * * *

List of Items Controlled

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Items:

* * * * *

e. Steam, gas or vapor sterilizable freeze-drying equipment with a condenser capacity of 10 kg of ice or greater in 24 hours (10 liters of water or greater in 24 hours) and less than 1000 kg of ice in 24 hours (less than 1,000 liters of water in 24 hours).

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g. * * *

g.2. Biocontainment chambers, isolators, or biological safety cabinets having all of the following characteristics, for normal operation:

g.2.a. Fully enclosed workspace where the operator is separated from the work by a physical barrier;

g.2.b. Able to operate at negative pressure;

g.2.c. Means to safely manipulate items in the workspace; *and*

g.2.d. Supply and exhaust air to and from the workspace is high-efficiency particulate air (HEPA) filtered.

Note 1 to 2B352.g.2: 2B352.g.2 controls class III biosafety cabinets, as specified in the WHO Laboratory Biosafety Manual (3rd edition, Geneva, 2004) or constructed in accordance with national standards, regulations or guidance.

Note 2 to 2B352.g.2: 2B352.g.2 does not control isolators “specially designed” for barrier nursing or transportation of infected patients.

h. Aerosol inhalation equipment designed for aerosol challenge testing with microorganisms, viruses or toxins, as follows:

h.1. Whole-body exposure chambers having a capacity of 1 cubic meter or greater.

h.2. Nose-only exposure apparatus utilizing directed aerosol flow and having a capacity for the exposure of 12 or more rodents, or two or more animals other than rodents, and closed animal restraint tubes designed for use with such apparatus.

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DATED: May 31, 2016

Kevin J. Wolf

Assistant Secretary

for Export Administration

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